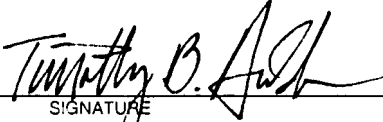


TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		CUSTOMER NO. 22,852 ATTORNEY'S DOCKET NUMBER <b>09707.0011-00000</b> U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/579,294</b>
INTERNATIONAL APPLICATION NO. <b>PCT/JP2004/017227</b>	INTERNATIONAL FILING DATE <b>November 12, 2004</b>	PRIORITY DATE CLAIMED <b>November 14, 2003</b>
TITLE OF INVENTION <b>CELL CULTURE METHOD, THREE-DIMENSIONAL CELL CULTURE METHOD, THREE-DIMENSIONAL TISSUE, ARTIFICIAL ORGAN AND TISSUE TRANSPLANTATION METHOD</b>		
APPLICANT(S) FOR DO/EO/US <b>1) Ryo SUDO ; 2) Kazuo TANISHITA ; 3) Mariko IKEDA ; 4) Toshihiro MITAKA</b>		
Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)).           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed with the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)).           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> </ol>		
Items 11 to 20 below concern document(s) or information included:		
<ol style="list-style-type: none"> <li>11. <input type="checkbox"/> Information Disclosure Statement under 37 CFR 1.97 and 1.98</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input type="checkbox"/> A preliminary amendment.</li> <li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A Substitute specification.</li> <li>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154 (d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4).</li> <li>20. <input checked="" type="checkbox"/> Other items or information: <b>Petition for Extension of Time (One Month)</b> <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> Copy of cover page of International Publication No. <b>WO 2005/047496 A1</b>.</li> <li>b. <input checked="" type="checkbox"/> Sequence Listing in hardcopy form.</li> <li>c. <input checked="" type="checkbox"/> Copy of Notification of Missing Requirements.</li> <li>d. <input checked="" type="checkbox"/> Sequence Listing Statement.</li> </ol> </li> </ol>		

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/579,294</b>		INTERNATIONAL APPLICATION NO. <b>PCT/JP2004/017227</b>		ATTORNEY'S DOCKET NUMBER <b>09707.0011-00000</b>	
The following fees have been submitted:				CALCULATIONS	PTO Use Only
21. <input type="checkbox"/> BASIC NATIONAL FEE (37 CFR 1.492(a)): .....\$300.00				\$	
22. <input type="checkbox"/> Examination fee (37CFR 1.492(c))					
If the Written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....\$0					
All other situations.....\$200				\$	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))					
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....\$0					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100					
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....\$400					
All other situations.....\$500				\$	
<b>TOTAL of 21, 22 and 23 =</b>				\$	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	Rate		
			x \$250.00	\$	
Extension of Time Fee (One Month)				\$ 120.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims			x \$50.00	\$	
Independent Claims			x \$200.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360.00	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 120.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$ - 60.00	
<b>SUBTOTAL =</b>				\$ 60.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest priority date (37 CFR 1.492(i)).				\$	
<b>TOTAL NATIONAL FEE =</b>				\$	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property.				\$	
<b>TOTAL FEE =</b>				\$ 60.00	
				Amount to be refunded:	\$
				charged:	\$
<p>a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>06-0916</u> in the amount of <u>\$60.00</u> to cover the above fee. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-0916</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p><b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p><b>SEND ALL CORRESPONDENCE TO:</b></p> <p>Finnegan, Henderson, Farabow, Garrett &amp; Dunner, L.L.P. 901 New York Avenue, N.W. Washington, DC 20001-4413</p> <div style="text-align: center; margin-top: 20px;">         SIGNATURE  <u>Timothy B. Donaldson, Reg. No. 43,592</u>        NAME/REGISTRATION NUMBER     </div> <p>DATED: June 4, 2007</p>					

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		<b>CUSTOMER NO. 22,852</b>  ATTORNEY'S DOCKET NUMBER <b>09707.0011-00000</b>  U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/579,294</b>
INTERNATIONAL APPLICATION NO. <b>PCT/JP2004/017227</b>	INTERNATIONAL FILING DATE <b>November 12, 2004</b>	PRIORITY DATE CLAIMED <b>November 14, 2003</b>
TITLE OF INVENTION <b>CELL CULTURE METHOD, THREE-DIMENSIONAL CELL CULTURE METHOD, THREE-DIMENSIONAL TISSUE, ARTIFICIAL ORGAN AND TISSUE TRANSPLANTATION METHOD</b>		
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Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)).           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed with the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)).           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> </ol>		
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## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/579,294	Ryo Sudo	09707.0011

INTERNATIONAL APPLICATION NO.	
PCT/JP04/17227	
I.A. FILING DATE	PRIORITY DATE
11/12/2004	11/14/2003

22852  
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

**RECEIVED**

MAR 05 2007

CONFIRMATION NO. 6583

371 FORMALITIES LETTER



\*OC000000022719016\*

Date Mailed: 03/02/2007

FINNEGAN, HENDERSON, FARABOW,  
GARRETT AND DUNNER, LLP

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 05/15/2006
- English Translation of the IA filed on 05/15/2006
- Copy of the International Search Report filed on 05/15/2006
- Preliminary Amendments filed on 05/15/2006
- Information Disclosure Statements filed on 05/15/2006
- Biochemical Sequence Diskette filed on 05/15/2006
- U.S. Basic National Fees filed on 05/15/2006
- Priority Documents filed on 05/15/2006
- Specification filed on 05/15/2006
- Claims filed on 05/15/2006
- Abstracts filed on 05/15/2006
- Drawings filed on 05/15/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

**SUMMARY OF FEES DUE:**

Total additional fees required for this application is **\$65** for a Small Entity:

- **\$65 Surcharge.**

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)**

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.  
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

TAMALA D HOLLAND

Telephone: (703) 308-9140 EXT 209

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/579,294	PCT/JP04/17227	09707.0011

## **STIC Biotechnology Systems Branch**

### **RAW SEQUENCE LISTING** **ERROR REPORT**

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number:

10/579,294

Source:

IFWP

Date Processed by STIC:

5-23-06

**THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.**

**PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:**

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,**
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY**

**FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221**

**TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.4.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:**

**<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>**

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

**Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:**

- 1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)**
- 2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**
- 3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05): U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314**

Revised 01/10/06



IFWP

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/579,294

DATE: 05/23/2006

TIME: 14:29:58

Input Set : A:\PTO.KD.txt

Output Set: N:\CRF4\05232006\J579294.raw

3 <110> APPLICANT: KEIO UNIVERSITY  
 5 <120> TITLE OF INVENTION: Methods of cell culture, cell 3D culture, and tissue transplantation, and  
 6 3D tissue  
 7 and artificial organ made thereby  
 9 <130> FILE REFERENCE: PCT835  
 C--> 11 <140> CURRENT APPLICATION NUMBER: US/10/579,294  
 C--> 11 <141> CURRENT FILING DATE: 2006-05-15  
 11 <150> PRIOR APPLICATION NUMBER: JP 2003/385677  
 12 <151> PRIOR FILING DATE: 2003-11-14  
 14 <160> NUMBER OF SEQ ID NOS: 12  
 16 <170> SOFTWARE: PatentIn version 3.1

Does Not Comply  
 Corrected Diskette Needed  
 (pg. 1-2)

## ERRORED SEQUENCES

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 157 <211> LENGTH: 20  
 158 <212> TYPE: DNA  
 159 <213> ORGANISM: Artificial Sequence  
 161 <220> FEATURE:  
 162 <223> OTHER INFORMATION: P12  
 164 <400> SEQUENCE: 12  
 165 tccaccaccc tggctgta  
 E--> 170 (continued from previous page)  
 E--> 171 (continued on next page)  
 E--> 174 (continued from previous page)  
 E--> 175 (continued on next page)

pls explain  
 source of genetic  
 material.

Invalid  
 Response

20

See item #11

on error  
 summary  
 sheet

pls delete

10/579,294

PAGE 2

<210> 1  
<211> 20  
<212> DNA  
<213> Artificial Sequence

PLS explain Source  
of genetic material.

<220>  
<223> Inventor: Sudo, Ryo  
Inventor: Tanishita, Kazuo  
Inventor: Ikeda, Mariko  
Inventor: Mitaka, Toshihiro

pls delete

<220>  
<223> P1

INVALID  
Response

<400> 1  
aaggcaccgc gattactccg

20

The above error is seen  
globally throughout the sequence.

See item # 11 on error  
Summary sheet.



RAW SEQUENCE LISTING ERROR SUMMARY  
PATENT APPLICATION: US/10/579,294

DATE: 05/23/2006  
TIME: 14:29:59

Input Set : A:\PTO.KD.txt  
Output Set: N:\CRF4\05232006\J579294.raw

Invalid Line Length:

The rules require that a line not exceed 72 characters in length. This includes spaces.

Seq#:1; Line(s) 5

## VERIFICATION SUMMARY

PATENT APPLICATION: US/10/579,294

DATE: 05/23/2006

TIME: 14:29:59

Input Set : A:\PTO.KD.txt

Output Set: N:\CRF4\05232006\J579294.raw

L:11 M:270 C: Current Application Number differs, Replaced Current Application No  
L:11 M:271 C: Current Filing Date differs, Replaced Current Filing Date  
L:170 M:334 E: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4  
L:171 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:12  
L:171 M:334 E: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4  
L:174 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:12  
L:174 M:334 E: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4  
L:175 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:12  
L:175 M:334 E: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4